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| APPLICATION NO. | FILING DATE                         | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------------------------------|----------------------|---------------------|------------------|
| 10/663,894      | 09/16/2003                          | Chi-Ming Che         | 9661-041-999        | 4526             |
| 32172           | 7590 11/29/20                       | 06                   | EXAM                | INER             |
|                 | N SHAPIRO LLP                       | GEMBEH, SHIRLEY V    |                     |                  |
|                 | JE OF THE AMERIO<br>, NY 10036-2714 | ART UNIT             | PAPER NUMBER        |                  |
|                 |                                     |                      | 1614                |                  |

DATE MAILED: 11/29/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

|  | Application No.  | Applicant(s)  |  |  |  |
|--|--|---|--|--|--|
|  | 10/663,894   | CHE, CHI-MING   |  |  |  |
| Office Action Summary  | Examiner   | Art Unit .  |  |  |  |
|  | Shirley V. Gembeh  | 1614  |  |  |  |
| The MAILING DATE of this communication<br>Period for Reply   | appears on the cover sheet wit   | h the correspondence address  |  |  |  |
| A SHORTENED STATUTORY PERIOD FOR RE WHICHEVER IS LONGER, FROM THE MAILING  - Extensions of time may be available under the provisions of 37 CF after SIX (6) MONTHS from the mailing date of this communication.  If NO period for reply is specified above, the maximum statutory pe Failure to reply within the set or extended period for reply will, by st Any reply received by the Office later than three months after the mearned patent term adjustment. See 37 CFR 1.704(b). | B DATE OF THIS COMMUNIC R 1.136(a). In no event, however, may a re riod will apply and will expire SIX (6) MONT atute, cause the application to become ABA | ATION.  ply be timely filed  THS from the mailing date of this communication.  ANDONED (35 U.S.C. § 133). |  |  |  |
| Status   |  |   |  |  |  |
| Responsive to communication(s) filed on 7 2a)    This action is <b>FINAL</b> . 2b)   | This action is non-final.<br>owance except for formal matte  | •   |  |  |  |
| Disposition of Claims  | •  |   |  |  |  |
| 4)   | 57 and 60-63 is/are withdrawn<br>3-35,37, 55 and 58-59 is/are r  | from consideration.   |  |  |  |
| Application Papers   |  |   |  |  |  |
| 9) The specification is objected to by the Exar  | niner.   |   |  |  |  |
| 10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner.   |  |   |  |  |  |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  |  |   |  |  |  |
| Replacement drawing sheet(s) including the co  |  |   |  |  |  |
| Priority under 35 U.S.C. § 119   |  |   |  |  |  |
| 12) Acknowledgment is made of a claim for force a) All b) Some * c) None of:  1. Certified copies of the priority docum 2. Certified copies of the priority docum 3. Copies of the certified copies of the application from the International But * See the attached detailed Office action for a  | nents have been received.<br>nents have been received in Appriority documents have been<br>priority documents have been<br>reau (PCT Rule 17.2(a)).        | oplication No received in this National Stage   |  |  |  |
|  | •  |   |  |  |  |
| Attachment(s)  1) Notice of References Cited (PTO-892)   | A) Intension 9   | ummary (PTO-413)  |  |  |  |
| 2) Notice of References Cited (PTO-692)  Notice of Draftsperson's Patent Drawing Review (PTO-948)  Information Disclosure Statement(s) (PTO-1449 or PTO/SI Paper No(s)/Mail Date   | Paper No(s   | )/Mail Date  formal Patent Application (PTO-152)  |  |  |  |

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## **DETAILED ACTION**

The response filed September 7, 2006 presents remarks and arguments to the office action mailed June 7, 2006. Applicants' arguments, filed, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

## Status of claims

Claims 1-4, 6-7, 9-11, 13, 25-28, 30, 31, 33-35, 37, 55, 58 and 59 are pending.

Claims 14-24, 38-54, 56-57 and 60-63 are withdrawn.

Claims 1, 25, 55, and 58 are amended.

Claims 5, 8, 12, 29, 32, and 36 are cancelled.

## Maintained Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 1-4, 6-7, 9-11, 13, 25-28, 30-31, 33-35,37, 55 and 58-59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wheelhouse et al. US 6,087,493 in view of Argyris et al. J. biological chem.

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Applicant traverses that (i) Wheelhouse teaches or discloses cationic porphyrins that inhibit telomerase activities and does not disclose a method that directly induces apoptosis in cancer cells (see page 20 of remarks) (ii) that the reference does not teach inhibition of reverse transcriptase of human immunodifficiency virus type 1 (HIV-1). In response, (i) Wheehouse teaches both cationic and negatively charged substituents

(see cols. 53 and 54, lines 45+) R is

. As to the reference, not

disclosing apoptosis is traversed, because (see col. 2, lines 10-25), it clearly teaches

The telomeres are multiple tandem repeats of a highly conserved DNA sequence (in mammals 5'-TTAGGG-3') (SEQ ID NO:3) found at the ends of chromosomes and in human germline cells the telomeres may be 15-25 kilobases 10 long. The telomeres are dynamic structures responsible for chromosome stability and have a role in control of chromosome separation and are thus involved in regulation of the cell cycle. The end replication problem means that with each cell division about 60-100 bases are lost from the ends of the <sup>21</sup> 15 chromosomes and as the telomeres shorten, cells eventually reach crisis and apoptosis is triggered. In immortal cell lines (tumors, germline and stem cells), an unusual enzyme activity—telomere terminal transferase, telomerase—is active which maintains the telomere length just above the 1- 20 crisis level. Whether telomerase activation is a cause or effect of the neoplastic state remains a matter of debate. However, the observation that telomerase is active in almost all tumor cells but not in most normal tissues does mean that telomerase presents a potentially highly selective target for 25 the design of new agents to interfere with the growth of tumor cells.

how apoptosis is arrived at

ЧП

Accordingly, the snagged information teaches in short that cells with long telomeres showed an incremental decrease in replicative capacity, whereas cells with short telomeres demonstrated apoptosis.

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As to (ii), all the claim limitation does not have to be met by one reference, as this is a 103 type rejection, it gives one of skill to combine teachings or disclosure at the time the claimed invention was made to be able to make and use the claim invention.

Thus the reason why another reference was used to show obviousness.

Next, Applicant argues that among the metals tested AuIII exhibited only 23% telomerase inhibition compared to the others H2 or ZnII. (see page 21 of remarks).

In response, inhibition is inhibition, the claims do not indicate at what extent inhibition is carried out, if Applicants' argument is what percentage of inhibition is seen when the claimed invention is used then it need to be as part of the claim invention. Applicants remarks (see page 322) states that stabilization of gold (III) or AU(III) and no acute cytotoxicity is found is also disclosed in the teaching of Wheehouse (see col. 16, lines 45-65). As to intercalation, (see remarks page 22, para. 1), the reference clearly teaches that compounds of such are known to intercalate with DNA (see col. 17, lines 38+).

With regards to the argument (see page 23, para.3, that Argyris does not disclose Au(III) and combination of both references does not render the claim invention obvious.

In response, Argyris, does not have to teach (Au(III)), the Wheelhouse reference teaches the different metal ions that are capable of such a function (see col. 3, lines 15+) one skilled in the art would have been motivated to substitute Zn for Au and would have expected a successful result in doing so.

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Applicant's arguments filed have been fully considered but they are not persuasive. (See above reasons).

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shirley V. Gembeh whose telephone number is 571-272-8504. The examiner can normally be reached on 8:30 -5:00, Monday- Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SVG 11/21/06

ARDIN H. MARSCHEL SUPERVISORY PATENT EXAMINER